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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,043	RAPAPORT, ELIEZER	
	Examiner	Art Unit	
	JAMES D. ANDERSON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-12 and 14-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-12 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Applicants' response and amendments to the claims, filed 10/31/2008, are acknowledged and entered. Claims 4-12 and 14-16 are pending and under examination.

Claim Rejections - 35 USC § 112 – 1st Paragraph – New Ground of Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 4 and 5 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (New Matter), is **withdrawn** in light of Applicant's amendments.

Claims 5-6, 8-12, and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1st "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The amended claims are drawn to methods for obtaining weight loss or maintaining weight reduction consisting of administering a first member selected from a group consisting of caffeine and theophylline and a second member selected from a group consisting of (a) adenosine and inorganic phosphate; b) adenosine 5'-monophosphate; and (c) adenosine 5'-triphosphate. The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*,

80 USPQ 448, 450 (Bd. App. 1948) ("consisting of" defined as "closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith."). Applicant's introduction of the limitation "consisting of" introduces new matter into the claims that is not supported by the disclosure.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117).

Lack of Ipsis Verbis Support

The present application is void of support for the newly claimed methods consisting of administration of a first member selected from a group consisting of caffeine and theophylline and a second member selected from a group consisting of (a) adenosine and inorganic phosphate; b) adenosine 5'-monophosphate; and (c) adenosine 5'-triphosphate. The instant specification discloses pharmaceutical and therapeutic compositions of ATP suitable for oral administration such pills along with fillers, binders, stabilizers, and enteric coating materials (page 5, lines 31-37). Applicant discloses administration of adenosine using an ATP oral dosage form (e.g., pill) (page 6, lines 1-4) having enteric coatings (id. at lines 26-36). Specific formulations disclosed in the specification include ATP, microcrystalline cellulose, maltodestrin, magnesium stearate, and silica (page 8, line 30 to page 9, line 6). Applicant discloses administration of these ATP pills to patients. The pills were also administered to coffee drinkers. Nowhere does Applicant recite a method "consisting of" administering a first member selected from a group consisting of caffeine and theophylline and a second member selected from a group consisting of (a) adenosine and inorganic phosphate; b) adenosine 5'-monophosphate; and (c) adenosine 5'-triphosphate.

Lack of Implicit or Inherent Support

Section 2163 of the MPEP states: "While there is no *in haec verba* requirement, newly added claim limitation must be supported in the specification through express, implicit, or inherent disclosure".

As discussed supra, the instant specification discloses pharmaceutical and therapeutic compositions of ATP suitable for oral administration such pills along with fillers, binders, stabilizers, and enteric coating materials (page 5, lines 31-37). Applicant discloses

administration of adenosine using an ATP oral dosage form (e.g., pill) (page 6, lines 1-4) having enteric coatings (id. at lines 26-36). Specific formulations disclosed in the specification include ATP, microcrystalline cellulose, maltodestrin, magnesium stearate, and silica (page 8, line 30 to page 9, line 6). Applicants discloses that administration of ATP pills containing ATP, microcrystalline cellulose, maltodestrin, magnesium stearate, and silica leads to weight loss. However, nowhere does Applicant propose to limit the administration of ATP to only ATP in free form.

As such, one skilled in the art would not conclude that the instant specification provides adequate support for methods consisting of administration of a first member selected from a group consisting of caffeine and theophylline and a second member selected from a group consisting of (a) adenosine and inorganic phosphate; b) adenosine 5'-monophosphate; and (c) adenosine 5'-triphosphate. In view of the teachings of the instant specification, one would conclude that Applicant intended that ATP would be administered in pills containing other excipients.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 5-6, 8-9, and 14-16 under 35 U.S.C. 103 as being unpatentable over Rapaport and Astrup is **withdrawn** in light of Applicant's amendments to claims 5, 6, and 14-16. The combined references teach and suggest the use of ATP (Rapaport) and ephedrine and caffeine (Astrup) to treat diabetes mellitus and complications thereof such as overweight. However, the instant claims have been amended to exclude the administration of anything other than those agents recited in the claims. As such, the administration of a composition comprising ephedrine as taught by Astrup is excluded from the instantly claimed methods.

Claims 4, 7, and 10-12 are again rejected under 35 U.S.C. 103(a) as being unpatentable over **Rapaport** (USP No. 5,547,942; Issued Aug. 20, 1996) (cited in IDS filed 5/12/2005) and **Astrup** (U.S. Patent No. 5,422,352; Issued Jun. 6, 1995) (previously cited by the Examiner).

Rapaport teaches methods of elevating extracellular levels of ATP for achieving stimulation of insulin secretion and for the treatment of patients suffering from non-insulin-dependent diabetes mellitus and their chronic clinical implications (Abstract). In this regard, Rapaport teaches the treatment of patients suffering from diabetes mellitus and its clinical complications a member selected from the group consisting of: (a) a mixture of adenosine and inorganic phosphate; (b) an adenine nucleotide such as AMP, ADP, and ATP (col. 6, lines 11-25). Effective doses are taught to be in the range of 0.1-100 mg/kg body weight per 24 hours for oral or topical administration and 0.01-10 mg/kg of body weight per 24 hours for injections, thus explicitly teaching and/or obviating the doses and administration routes as recited in the instant claims. Rapaport is silent with respect to caffeine and theophylline and obtaining weight loss.

However, Astrup teaches compositions comprising caffeine and ephedrine for the purpose of reducing weight of a human (Abstract). With regard to diabetes mellitus as taught in Rapaport, Astrup teaches that obesity is accompanied by a number of health hazards such as diabetes mellitus, which is more common in overweight people than in individuals of normal weight (col. 1, lines 36-45). Thus, obesity is taught to contribute to morbidity and mortality in individuals suffering from, *e.g.*, diabetes mellitus (*id.* at lines 45-48). Astrup thus teaches a method of treating complications to overweight or obesity such as diabetes mellitus (col. 5, lines 17-33; col. 11, lines 30-34) comprising administering a thermogenically active and/or appetite-reducing adrenergic agonist (*e.g.*, ephedrine) and a thermogenically active xanthine (*e.g.*,

caffeine). Theophylline is also taught to be a reasonable substitute for caffeine, as both are thermogenically active xanthines (col. 6, line 65 to col. 7, line 6). The amount of caffeine or other xanthine is taught to be in the range of 80 mg to 1.9 grams per unit dose, preferably 80 mg to 720 mg, and can be administered 1 to 10 times daily, thus obviating the instantly claimed 0.1-100 mg/kg/day and 0.1-10 mg/kg/day (col. 8, lines 52-59). The compositions are administered "by any suitable route" such as orally, topically, or parenterally, thus obviating the claimed "oral", "injection", and topical administration routes (col. 8, lines 60-66).

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to administer ephedrine/caffeine and a mixture of adenosine and inorganic phosphate or an adenine nucleotide such as AMP, ADP, and ATP to overweight patients with diabetes mellitus in the doses and administration routes instantly claimed. The skilled artisan would have been motivated to do so because Rapaport teaches that mixtures of adenosine and inorganic phosphate or an adenine nucleotide such as AMP, ADP, and ATP are useful in treating diabetes mellitus and complications thereof and Astrup teaches that obesity contributes to the morbidity and mortality in individuals suffering from, *e.g.*, diabetes mellitus, and thus teaches administration of ephedrine/caffeine for treating complications to overweight or obesity such as diabetes mellitus. As such, the skilled artisan would have been imbued with at least a reasonable expectation that administration of ephedrine/caffeine to patients with diabetes mellitus would result in weight loss as taught by Astrup and mixtures of adenosine and inorganic phosphate or an adenine nucleotide such as AMP, ADP, and ATP as taught in Rapaport would treat chronic clinical complications of diabetes mellitus. One skilled in the art would reasonably expect that the effects of the individual methods taught in Astrup and Rapaport would be observed when the methods are combined into a single treatment regimen.

In support of the obviousness of the instantly claimed invention, the Examiner makes the following findings of fact:

(i) Rapaport teaches the treatment of diabetes mellitus and complications thereof comprising administering mixtures of adenosine and inorganic phosphate or an adenine nucleotide such as AMP, ADP, and ATP in the doses instantly claimed;

(ii) Astrup teaches the nexus between obesity and diabetes mellitus; and

(iii) Astrup teaches methods of reducing the weight of a human and treating complications to overweight or obesity such as diabetes mellitus comprising administering ephedrine and caffeine in the doses instantly claimed.

Accordingly, one skilled in the art looking to treat diabetes mellitus and complications thereof with mixtures of adenosine and inorganic phosphate or an adenine nucleotide such as AMP, ADP, and ATP as taught in Rapaport would have been motivated to also administer a composition that would reduce the weight of the patient having diabetes mellitus in order to treat one of the primary contributing factors of diabetes (*i.e.*, obesity).

Applicant's results have been carefully considered but they are not evidentiary of a result that would not be expected based on the teachings of the prior art. In this regard, Applicant demonstrates that the combination of ATP and caffeine results in the same weight loss as ATP administered alone. However, the administration of ATP to a patient with diabetes mellitus as taught in Rapaport would be expected to necessarily result in weight loss as instantly claimed because the same composition is being administered in the same dose to patients.

Applicant's arguments have been carefully considered but they are not deemed persuasive. Applicant argues that Astrup suggests that ephedrine is an essential compound for the treatment disclosed therein. Applicant asserts that the independent claims specifically exclude ephedrine because ephedrine is not recited as causing weight loss. This argument is not persuasive because claim 4 allows for the administration of other active agents. The fact that Applicant states that "weight loss is caused by administering the first member and the second member" does not preclude weight loss also being caused by additional active agents in addition to those agents explicitly recited in the claims.

Applicant further argues that there are severe health complications caused by ephedrine and the final rule issued by the FDA prohibits the sale of dietary supplements containing ephedrine alkaloids (ephedra). However, the actions of the FDA have no bearing on the prosecution of patent applications. The Examiner respectfully requests that Applicant provide supporting case law establishing that banning of an agent by the FDA precludes the Patent Office from making art rejections against methods that encompass administration of the banned agent.

Applicant further argues that the Office Action made an insufficient showing for a motivation to combine Rapaport and Astrup. In this regard, Applicant submits that treating

complications to overweight or obesity has nothing to do with suggesting treatment of overweight or obesity themselves. Applicant asserts that since there are 66% of the population overweight and only a maximum of 7.8% with diabetes, the treatment of diabetes can not suggest a treatment of obesity or overweight. In response, the Examiner respectfully submits that Rapaport and Astrup teach and suggest that their compositions can be used to treat diabetes. As such, there would clearly be overlap between such patients and those overweight patients recited in the instant claims. It is this patient population (those diabetes patients that are overweight), which is encompassed by the instant claims, that is obvious over the cited prior art.

Accordingly, the claims are deemed properly rejected for the reasons of record and as reiterated above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 5-6, 8-9, and 14-16 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 5,547,942 in view of Astrup (U.S. Patent No. 5,422,352; Issued Jun. 6, 1995) is **withdrawn** in light of

Applicant's amendments to claims 5, 6, and 14-16. The combined references teach and suggest the use of ATP (Rapaport) and ephedrine and caffeine (Astrup) to treat diabetes mellitus and complications thereof such as overweight. However, the instant claims have been amended to exclude the administration of anything other than those agents recited in the claims. As such, the administration of a composition comprising ephedrine as taught by Astrup is excluded from the instantly claimed methods.

Claims 4, 7, and 10-12 are again rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 5,547,942 in view of Astrup (U.S. Patent No. 5,422,352; Issued Jun. 6, 1995). The claims of the '942 patent are drawn to methods of treating chronic diabetes mellitus in a human comprising administering a mixture of adenosine and inorganic phosphate or an adenine nucleotide such as AMP, ADP, or ATP. Astrup teaches compositions comprising caffeine and ephedrine for the purpose of reducing weight of a human (Abstract). With regard to diabetes mellitus as taught in Rapaport, Astrup teaches that obesity is disclosed as being accompanied by a number of health hazards such as diabetes mellitus, which is more common in overweight people than in individuals of normal weight (col. 1, lines 36-45). Thus, obesity is taught to contribute to morbidity and mortality in individuals suffering from, e.g., diabetes mellitus (id. at lines 45-48). Astrup thus teaches a method of treating complications to overweight or obesity such as diabetes mellitus (col. 5, lines 17-33; col. 11, lines 30-34). As such, it would have been obvious to one of ordinary skill in the art to combine the treatment methods of the '942 patent and Astrup to administer a mixture of adenosine and inorganic phosphate or an adenine nucleotide such as AMP, ADP, or ATP and ephedrine/caffeine to a patient having diabetes mellitus as recited in the claims of the '942 patent.

Applicant's arguments have been carefully considered but they are not persuasive. Applicant asserts that the present rejection is improper per se and fails to comply with applicable rules and regulations. In this regard, Applicant takes issue with the fact that the Examiner has cited a secondary reference in support of the present rejection. However, it is entirely proper for the Examiner to cite a secondary reference in support of a nonstatutory obviousness-type double patenting rejection if the secondary reference provides one skilled in the art with the means and

motivation to modify the method claimed in the cited patent to arrive at the claimed invention. In the instant case, Astrup is provided at evidence that at the time the instant application was filed, it was known in the art that compositions comprising caffeine and/or theophylline could be used to reduce weight in patients with diabetes. As such, addition of such compositions to those recited in the '942 patent would have been an obvious modification of the '942 patent claim methods of treating diabetes.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614